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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,311	04/28/2006	Koh-Ichi Sakata	1603/2	1552

25297 7590 04/19/2007

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EXAMINER	
GUSSOW, ANNE	
ART UNIT	**PAPER NUMBER**
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,311	SAKATA ET AL.	
	Examiner	Art Unit	
	Anne M. Gussow	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *1-5,9 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/17/06, 2/7/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group III, claims 6-8, in the reply filed on March 1, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-5 and 9-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 1, 2007.

3. Claims 6-8 are under examination.

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on January 17, 2006 and February 7, 2007 have been fully considered and an initialed copy of the IDS is included with this Office Action.

Specification

5. The use of the trademark Lymphoprep™ has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The trademark symbols have not been included for trademarks in this application. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 6-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting or diagnosing cancer in cervical, uterine, lung, and breast cancer, does not reasonably provide enablement for determining cancer susceptibility in just any cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims are broadly drawn to determining cancer susceptibility for just any cancer by measuring DNA-dependent protein kinase activity in cells derived from a test

subject and comparing the DNA-dependent protein kinase activity in cells derived from the test subject to activity in cells derived from a healthy subject, wherein the cells are lymphoid cells.

The specification discloses measurement of DNA-dependent protein kinase activity in patients with breast, uterine, head and neck cancer or malignant lymphoma (example 2 pages 23-24 and figure 2). The specification does not provide any direction or guidance to assist one skilled in the art in the determination of susceptibility to cancer. The specification does not provide any direction or guidance to assist one skilled in the art in the measurement of DNA-dependent protein kinase activity levels in just any cancer.

Someya, et al. (Carcinogenesis, 2006. Vol. 27 No. 1, pages 117-122, as cited on the IDS) teach detection of DNA-dependent protein kinase activity at significantly lower levels than normal subjects in patients with uterine cervix cancer and breast cancer (page 119 and figure 1A). Someya, et al. teach patients with head and neck cancer, esophageal cancer, and malignant lymphoma had no significant difference in DNA-dependent protein kinase activity from normal volunteers (page 119 and figure 1A). Susceptibility is defined as "likelihood of an individual to develop ill effects from an external agent" (Stedman's Medical Dictionary).

There is insufficient evidence or nexus that would lead the skilled artisan to predict the ability to determine susceptibility to just any cancer by measuring DNA-dependent protein kinase activity. The specification does not teach the likelihood of an

individual to develop cancer. The specification does not teach levels of DNA-dependent protein kinase activity in just any cancer type compared to healthy samples.

In view of the lack of predictability of the art to which the invention pertains, the lack of established guidelines for determining cancer susceptibility and measuring DNA-dependent protein kinase activity in just any cancer type, undue experimentation would be required to practice the claimed methods with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed methods and absent working examples providing evidence which is reasonably predictive that the claimed methods are effective for determining the susceptibility to just any cancer commensurate in scope with the claimed invention.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogawa, et al. (EP 1184665A1, published March 6, 2002, as cited in previous Office Action).

The claims recite a method for determining cancer susceptibility by measuring DNA-dependent protein kinase activity in cells derived from a test subject wherein the cells are lymphoid cells.

Ogawa, et al. teach a method for measuring protein kinase activity in a test sample consisting of the steps of contacting the sample with a substrate peptide phosphorylated by the protein kinase under conditions necessary for the phosphorylation reaction and detecting a change in the phosphorylation level of the substrate peptide based on the change in reactivity of the substrate peptide with an antibody that identifies the phosphorylation site of the substrate peptide (page 3, lines 44-50), wherein the sample is obtained from tissue samples, blood, urine, body fluids, sweat, saliva, and body secretions such as milk (page 8 lines 7-10). Since the only active step of the claimed method is measuring protein kinase activity, and Ogawa, et al. teach measuring protein kinase activity, all the limitations of the claims have been met.

10. Claims 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Auckley, et al. (Carcinogenesis, 2001. Vol. 22 No. 5, pages 723-727, as cited on the IDS).

The claims have been described supra.

Auckley, et al. teach DNA-dependent protein kinase activity is reduced in blood samples from lung cancer patients compared to control non-lung cancer patients (bottom of page 724 to page 725 top of 2nd column, and figure 2). Since, Auckley, et al. teach the same method steps as the instant application and the claims do not define the

specific cancer susceptibility determined by the method, all the limitations of the claims have been met.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow, Ph.D.

April 9, 2007

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER